

II. CLAIM AMENDMENTS

1. (Original) An abuse-proofed, thermoformed dosage form, characterised in that, in addition to one or more active ingredients with abuse potential (A) optionally together with physiologically acceptable auxiliary substances (B), it contains at least one synthetic or natural polymer (C) and optionally at least one wax (D), wherein component (C) exhibits a breaking strength of at least 500 N.
2. (Original) A dosage form according to claim 1, characterised in that it is in the form of a tablet.
3. (Original) A dosage form according to claim 1, characterised in that it is in multiparticulate form, preferably in the form of microtablets, micropellets, granules, spheroids, beads or pellets, optionally pressed into tablets or packaged in capsules.
4. (Currently Amended) A dosage form according to claim 1, characterised in that the polymer (C) used is at was. At least one polymer selected from the group consisting of polyethylene oxide, polymethylene oxide, polypropylene oxide, polyethylene, polypropylene, polyvinyl chloride, polycarbonate, polystyrene, polyacrylate, copolymers and the mixtures thereof, preferably polyethylene oxide.
5. (Previously Presented) A dosage form according to claim 1, characterised in that the polymer (C) has a molecular weight of at least 0.5 million according to rheological measurements.

6. (Original) A dosage form according to claim 5, characterised in that the molecular weight is 1-15 million.

7. (Previously Presented) A dosage form according to claim 1, characterised in that the wax (D) is at least one natural, semi-synthetic or synthetic wax with a softening point of at least 60°C.

8. (Original) A dosage form according to claim 7, characterised in that the wax (D) is carnauba wax or beeswax.

9. (Previously Presented) A dosage form according to claim 1, characterised in that the component(s) (C) is/are present in quantities such that the dosage form has a breaking strength of at least 500 N.

10. (Previously Presented) A dosage form according to claim 1, characterised in that the active ingredient (A) is at least one active ingredient selected from the group consisting of opiates, opioids, tranquillisers, stimulants, barbiturates and further narcotics.

11. (Previously Presented) A dosage form according to claim 1, characterised in that it additionally comprises at least one of the following components a) -f):

(a) at least one substance which irritates the nasal passages and/or pharynx,

(b) at least one viscosity-increasing agent, which, with the assistance of a necessary minimum quantity of an aqueous liquid, forms a gel with

the extract obtained from the dosage form, which gel preferably remains visually distinguishable when introduced into a further quantity of an aqueous liquid,

c) at least one antagonist for the active ingredient or active ingredients with abuse potential

(d) at least one emetic,

(e) at least one dye as an aversive agent,

(f) at least one bitter substance.

12. (Original) A dosage form according to claim 11, characterised in that the component (a) irritant substance causes burning, itching, an urge to sneeze, increased formation of secretions or a combination of at least two of these stimuli.

13. (Previously Presented) A dosage form according to claim 1, characterised in that the component (a) irritant substance is based on one or more constituents of at least one hot substance drug.

14. (Original) A dosage form according to claim 13, characterised in that the hot substance drug is at least one drug selected from the group consisting of Allii sativi bulbus (garlic), Asari rhizoma cum herba (Asarum root and leaves), Calami rhizoma (calamus root), Capsici fructus (capsicum), Capsici fructus acer (cayenne pepper), Curcumae longae rhizoma (turmeric root), Curcumae xanthorrhizae rhizoma (Javanese turmeric root), Galangae rhizoma (galangal root), Myristicæ semen (nutmeg), Piperis nigri fructus (pepper), Sinapis albae semen (erucae/white mustard seed), Sinapis nigri semen (black

mustard seed), Zedoariae rhizoma (zedoary root) and Zingiberis rhizoma (ginger root), particularly preferably at least one drug selected from the group consisting of Capsici fructus (capsicum), Capsici fructus acer (cayenne pepper) and Piperis nigri fructus (pepper).

15. (Previously Presented) A dosage form according to claim 13, characterised in that the constituent of the hot substance drug is an o-methoxy(methyl)phenol compound, an acid amide compound, a mustard oil or a sulfide compound or is derived from such a compound.

16. (Previously Presented) A dosage form according to claim 13, characterised in that the constituent of the hot substance drug is at least one constituent selected from the group consisting of myristicin, elemicin, isoeugenol, t3-asarone, safrole, gingerols, xanthorrhizol, capsaicinoids, preferably capsaicin, piperine, preferably trans-piperine, glucosinolates, preferably based on non-volatile mustard oils, particularly preferably based on p-hydroxybenzyl mustard oil, methylmercapto mustard oil, methylsulfonyl mustard oil and a compound derived from these constituents.

17. (Previously Presented) A dosage form according to claim 11, characterised in that component (b) is at least one viscosity-increasing agent selected from the group consisting of microcrystalline cellulose with 11 wt.% carboxymethylcellulose sodium (Avicel® RC 591), carboxymethylcellulose sodium (Blanose®, CMC-Na C300P®, Frimulsion BLC-5®, Tylose C300 P®), polyacrylic acid (Carbopol® 980 NF, Carbopol® 981), locust bean flour (Cesagum® LA-200, Cesagum® LID/150, Cesagum® LN-1), citrus pectin (Cesapectin® HM Medium Rapid Set), waxy maize starch (C*Gel

04201®), sodium alginate Frimulsion ALG (E401)®, guar flour(Frimulsion BM®, Polygum 26/l-75®), iota carrageen (Frimulsion D021®), karaya gum, gellan gum (Kelcogel F®, Kelcogel LT100®), galactomannan (Meyprogat 150 ®), tara bean flour (Polygum 43/i®), propylene glycol alginate (Protanal-Ester SD-LB®), sodium hyaluronate, apple pectin, pectin from lemon peel, sodium hyaluronate, tragacanth, tara gum (Vidogum SP 200®), fermented polysaccharide welan gum (K1A96) and xanthan gum (Xantural 180®).

18. (Previously Presented) A dosage form according to claim 11, characterised in that component (c) is at least one opiate or opioid antagonist selected from the group consisting of naloxone, naltrexone, nalmefene, nalid, nalmexone, nalorphine, naluphine and a corresponding physiologically acceptable compound, in particular a base, salt and solvate.

19. (Previously Presented) A dosage form according to claim 11, characterised in that the component (c) used is at least one neuroleptic as a stimulant antagonist, preferably selected from the group consisting of haloperidol, promethazine, fluphenazine, perphenazine, levomepromazine, thioridazine, perazine, chiorpromazine, chlorprothixine, zuclopentixol, flupentixol, prothipendyl, zotepine, benperidol, pipamperone, melperone and bromperidol.

20. (Previously Presented) A dosage form according to claim 11, characterised in that the component (d) emetic is based on one or more constituents of radix ipecacuanha (ipecac root), preferably on the constituent emetine, and/or is apomorphine.

21. (Previously Presented) A dosage form according to claim 11, characterised in that component (e) is at least one physiologically acceptable dye.

22. (Previously Presented) A dosage form according to claim 11, characterised in that component (f) is at least one bitter substance selected from the group consisting of aromatic oils, preferably peppermint oil, eucalyptus oil, bitter almond oil, menthol and mixtures thereof, fruit aroma substances, preferably from lemons, oranges, limes, grapefruit and mixtures thereof, denatonium benzoate and mixtures thereof.

23. (Previously Presented) A dosage form according to claim 11, characterised in that the active ingredient or active ingredients (A) is/are spatially separated from component (c) and/or (d) and/or (f), wherein the active ingredient or active ingredients (A) is/are preferably present in at least one subunit (X) and components (c) and/or (d) and/or (f) is/are present in at least one subunit (Y), and, when the dosage form is correctly administered, components (c) and/or (d) and/or (f) from subunit (Y) do not exert their effect in the body and/or on taking.

24. (Previously Presented) A dosage form according to claim 1, characterised in that it contains at least one active ingredient at least partially in controlled release form.

25. (Original) A dosage form according to claim 24, characterised in that each of the active ingredients with abuse potential (A) is present in a controlled release matrix.

26. (Original) A dosage form according to claim 25, characterised in that component (C) and/or component (D) also serve as a controlled release matrix material.

27. (Previously Presented) A process for the production of a dosage form according to claim 1, characterised in that components (A), (B), (C) and the optionally present component (D) and the optionally present components (a) to (f) are mixed, and

the resultant mixture, optionally after granulation, is press-formed to yield the dosage form with

preceding, simultaneous, or subsequent exposure to heat.

28. (Original) A process according to claim 27, characterised in that granulation is performed by means of a melt process.

29. (Currently Amended) A dosage form according to claim 1 obtainable by a process Wherein wherein components (A), (B), (C) and the optionally present component (D) and the optionally present components (a) to (f) are mixed, and the resultant mixture, optionally after granulation, is press-formed to yield the dosage form with preceding, simultaneous, or subsequent exposure to heat.